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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,852	02/19/2002	Jeremy Marshall	3003-1004	2432

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Path

Office Action Summary	Application No.	Applicant(s)	
	10/049,852	MARSHALL ET AL.	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 9, 11-13, 18 and 21 is/are rejected.
- 7) ☐ Claim(s) 6, 7, 10, 14-17 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2,8, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,569,189 to Parsons. Parsons discloses an embodiment in Figure 5a that includes:

A barrel 30;

“means for carrying a lancet” (4) at the forward part of the barrel;

hammer 232;

barrier 42' to the rear of the hammer;

spring 234 acting between the hammer and barrier;

and a trigger 58.

The limitation “means for carrying a lancet” is met by the cylindrical structure (4) at the forward end of the barrel. The cylinder (4) is hollow and capable of accommodating a lancet. Parsons explains that the barrier (42') acts as a means for adjusting the degree of compression of the spring. Column 9, lines 10-15 state that the barrier can be used to “selectively shorten or lengthen the channel.” The barrier is adjusted by rotation, which is inherently performed by the user. Lines 21-28 of column 9 further describe the barrier. The corresponding threads of the barrier and barrel are considered to meet the limitations of claim 2.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1,2,4, 8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,045,567 to Taylor et al. in view of Parsons.

Taylor discloses a lancet device that includes:

- barrel 16;
- means for carrying a lancet 40;
- hammer 26C;
- barrier 18 to the rear of the hammer;
- spring 22 acting between the hammer and barrier;
- and trigger 26.

Taylor explains that the barrier (18) at the rear of the device can be manually adjusted. The barrier is connected to the device by helical threads (column 2, lines 48-52). The axial position of the barrier determines the depth of penetration of the lancet (column 3, lines 20-26). Taylor fails to form the barrier so that it adjusts the compression of the spring (22). Parsons discloses another device with a similar barrier (42') located at the rear of an injection device. The devices are analogous, because they are both used to puncture skin and have very similar structures. Also, both barriers are connected to the body by helical threads and can be adjusted by the operator. Parsons teaches that such a barrier (42') can be used to adjust the degree of compression of the drive spring. Column 9, lines 10-15 state that the barrier can be used to "selectively shorten or lengthen the channel." Since the compression of a spring determines the length of its extension, the compression of a drive spring would also affect the depth of penetration of a lancet. It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the barrier of

Art Unit: 3731

the Taylor device to adjust the compression of the drive spring, as taught by Parsons, as this would allow the operator to further adjust the depth of penetration of the lancet to accommodate the needs of various patients.

Regarding claim 2: Even though the barrier is formed with slots (18b) and the barrel has projections, it would be an obvious matter of design choice to switch the slots to be formed in the barrel and the projections to be formed on the barrier. Both configurations allow the barrier to be adjusted axially by rotation.

Regarding claim 4: Taylor teaches that protuberances (18a) formed on the barrier should be resilient for shock absorption (column 4, lines 5-12).

3. Claims 5,9,13,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Parsons, as applied above, and further in view of US Patent No. 5,871,494 to Simons.

The modified Taylor device fails to include a sleeve spring at the rear of the barrel. Simons teaches that a cocking mechanism can be in the form of a sleeve (562) on the rear portion that is spring (568) urged forwardly. The sleeve (562) retracts the hammer (546) when pulled back and disconnects from the hammer when released and moved forward (column 12, lines 16-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sleeve spring at the rear portion of the barrel of the modified Taylor device, as Simons teaches that this structure provides a cocking mechanism for the drive spring.

Taylor fails to use a lancet carrying means that spring urges the lancet tip rearwardly. Simons forms the lancet carrying means as a tubular member that is spring (228) urged rearwardly, wherein the lancet (216) fits into the forward end of the

Art Unit: 3731

carrying means (Figure 3C-D). Simons teaches that this structure exposes the lancet only when actuated, so that the user is protected against accidental pricks and scratches (column 9, lines 17-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a lancet carrier in the modified Taylor device that normally biases the lancet rearwardly, as Simons teaches that this prevents the user from being accidentally pricked or scratched by the lancet tip.

4. Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Parsons, as applied to claim 2 above, and further in view of US Patent No. 5,318,584 to Lange et al.

Taylor and Parsons fail to disclose an adjustment mechanism with slots that have non-skew portions. Lange discloses another lancet device with an adjustment mechanism in the form of a cooperating slot (42) and projection (59). Lange teaches that the skewed slot can have a non-skewed section (41) so that the user can lock the longitudinal position of the moveable member is so desired (column 6, lines 65-68). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the adjustment mechanism of the modified Taylor device to have a non-skewed portion, as Lange teaches that this allows a specific longitudinal position to be maintained.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Parsons and Lange, as applied to claim 3 above, and further in view of Simons.

The modified Taylor device fails to include a sleeve spring at the rear of the barrel. Simons teaches that a cocking mechanism can be in the form of a sleeve (562)

Art Unit: 3731

on the rear portion that is spring (568) urged forwardly. The sleeve (562) retracts the hammer (546) when pulled back and disconnects from the hammer when released and moved forward (column 12, lines 16-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sleeve spring at the rear portion of the barrel of the modified Taylor device, as Simons teaches that this structure provides a cocking mechanism for the drive spring.

Allowable Subject Matter

6. Claims 6,7,10, 14-17 and 19 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments with respect to the combination of Bodicky and Parsons have been considered but are moot in view of the new ground(s) of rejection. Contrary to applicant's assertions, "acting" on a lancet is quite different than "impacting" a lancet. Therefore, a new rejection has been made.

8. Applicant argues that lancet devices are not analogous to the Parsons hypodermic jet injector, but this is not persuasive. These two types of devices are quite similar in structure and function: 1) Both function to puncture skin; 2) All the devices include some type of trigger mechanism, a drive spring, and hammer. Therefore, they are considered to be analogous and the combinations are proper.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
8/17/05

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Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER